

REMARKS

Claims 15-46 are pending and rejected. Claim 15 is amended to correct antecedent basis, as requested. The specification has been amended to correct a typographical error on page 19.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 15-46 are rejected under 35 U.S.C. §112 ¶1 as containing subject matter not described in the specification so as to enable one skilled in the art to make and/or use the invention. Applicants request reconsideration for the following reasons.

The Examiner states

The claims are drawn to a method of performing a "phototherapeutic procedure". The term "therapy" (or phototherapy) implies an assertion that an ill patient can be treated such that manifestations of the illness are ameliorated.

As the examiner correctly notes, the claims recite "A method of performing a phototherapeutic procedure". By following the claimed steps, the procedure is performed: the procedure involves exposure of tissue with light of the claimed wavelength, and is performed to treat tumors and other lesions by causing cellular injury to the lesions (page 10, lines 4-5; page 14, lines 17-20). Hence, it is a "phototherapeutic" procedure. This is what is required by the claim.

Applicants respectfully disagree with the second sentence. The Examiner appears to be reading a particular end result or efficacy of the phototherapeutic procedure into applicants' claim language. Applicants' method describes and enables formulations (e.g. solutions, suspensions), doses (e.g. about 1

nM to about 0.5M), excipients (surfactants, buffers), routes of administration (e.g. parenteral, topical), exposure conditions (wavelength, fluence), at least at pages 18, line 17 to page 20, line 8.

Applicants respectfully disagree with the Examiner's statements directed to drugs and prodrugs: "If one takes a "drug" that has been shown to be effective in one way or another, and subsequently endeavors to create a "prodrug" thereof, "unpredictable" effects in vivo can result." (page 2 of the Office Action). The specification does not disclose a prodrug at all, and uses the term "drug" only with reference as a possible target binding moiety, and in mentioning the Food and "Drug" Administration (page 5, line 4; page 10, line 12). Applicants disclose a sulfenate photosensitizer; applicant does not state that this is a drug or a prodrug.

Applicants respectfully disagree with the Examiner's statements directed to singlet oxygen. Applicants specifically state that the claimed photosensitizers do not require oxygen for causing cellular injury; instead, they involve photoexcitation and direct energy transfer (page 5 lines 19-23; page 6, lines 11-13).

Type 1 photosensitizers do not require oxygen for causing cellular injury... The present invention discloses novel aromatic sulfenates that react mainly by a type 1 mechanism for phototherapy of tumors and other lesions.

Claims 15-46 are rejected under 35 U.S.C. §112 ¶2 as indefinite as to what the objectives might be, and what the manifestations of a successfully completed procedure might be. Applicants respectfully disagree.

35 U.S.C. §112 ¶2 requires that claims particularly point out and

distinctly claim the subject matter which the applicant regards as his invention. As analyzed previously, the claims recite "A method of performing a phototherapeutic procedure" by "the steps of (a) administering to a target tissue... a sulfenate photosensitizer" [of the required formula]", "and (b) exposing said target tissue with the light of wavelength between 300 and 950 nm with sufficient power and fluence rate to perform the phototherapeutic procedure."

The method of performing the procedure requires a first step (a), which administers to a target tissue in an animal an effective amount of the compound shown, and then a second step (b), which exposes the target tissue to light of the recited wavelength and under the recited conditions, to perform the procedure. Applicants respectfully assert that this does particularly point out and distinctly claim the subject matter which applicants regard as their invention, completely satisfying the requirements of 35 U.S.C. §112 ¶2. The Examiner's request for "objectives" and "manifestations of a successfully completed procedure" are not required by 35 U.S.C. §112 ¶2.

As part of this Amendment, applicants include a Declaration by Dr. Rajagopalan, one of the inventors. Dr. Rajagopalan analyzes the chemistry of the compound and how a phototherapeutic procedure will result when the method is performed, due to this chemistry. Hence, the method is predictable.

Dr. Rajagopalan also states his understanding of this method with respect to the Examiner's request for evidence "that an ill patient can be treated such that manifestations of the illness are ameliorated."

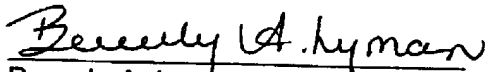
CONCLUSION

For the foregoing reasons, applicants' invention is believed to be patentable and an early Notice of Allowance is respectfully requested.

Applicant knows of no fee due with this submission. However, if any fees are necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to Deposit Account No. 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS. L.L.P.



Beverly A. Lyman
Reg. No. 41,961

2700 Carew Tower
441 Vine Street
Cincinnati, OH 45202
(513) 241-2324
(513) 421-7269 facsimile